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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,269	01/14/2004	George M. Halow	A-8051.CIP.RNFMP/bh	2686

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/756,269

Applicant(s)

HALOW, GEORGE M.

Examiner

Frank I. Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40, 42, 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as follows:

Claim 40 recites the limitation "the sodium phosphate is a powder" which renders the claims indefinite in that once dissolved in the PEG the sodium phosphate cannot be in powder form. Examiner suggests that Applicant amend the claim to indicate that prior to dissolving in PEG the sodium phosphate is a powder.

Claims 42 and 43 recites the limitation "no supplemental electrolytes". There is insufficient antecedent basis for this limitation in the claims in that claim 1 and claim 13 requires the presence of sodium phosphates which are electrolytes. As such, claims 42 and 43 cannot now claim that there are no supplemental electrolytes. Examiner suggests that Applicant amend claims 42 and 43 to indicate that other than the sodium phosphates there are no supplemental electrolytes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/43654 in view of Wood et al. (US Pat. 5,498,425) and Vining (US Pat. 5,782,762) in further view of Kaori et al. and Physician's Desk Reference (49th Ed. 1995).

WO 98/43654 teach a composition and method of purging the colon prior to colonoscopy, radiographic examination or bowel surgery containing sodium phosphate salts, including mono and dibasic salts) combined with polyethylene glycol, bisacodyl and cascara sagrada and that the composition can be administered in solid or liquid (aqueous) form (Pgs. 1, 7, 11). It is taught the combination of compounds are present in amounts effective to produce a purgative and/or laxative composition which evidences synergistic activity and that one of ordinary skill in the art may readily determine the amount and types of compounds/compositions to used in treating a particular patient (Pg. 11).

Wood et al. ('425) teach that cascara and bisacodyl are used for bowel clearance. It is taught that powders may be packaged in aluminum lined paper containers and that such packets are economical and easier to ship and store (Column 1, lines 6-12, Column 3, lines 4-7).

Vining teaches that in addition to using laxatives the patient should be put on a clear liquid diet to obtain a clean bowel for examination (Column 8, lines 1-20).

Kaori et al. disclose the combination of 45 ml of oral sodium phosphate (Fleet®) mixed with 45 ml of water and 1000 ml of PEG electrolyte lavage which was tolerated well and resulted in satisfactory cleansing of the colon (Abstract). It is disclosed that this modified method using smaller amount of oral lavage is useful in the preparation for colonoscopy (Abstract).

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Physician's Desk Reference (1995) discloses that 5 ml of regular or flavored Fleet® Phospho®-soda contains 2.4 g of monobasic sodium phosphate and .9 g of dibasic sodium phosphate and that 45 ml is used as a purgative (Pgs. 1018, 1019). It is disclosed that Golytely®, PEG-3350 and electrolytes for oral solution contain 236 grams of PEG-3350 which is in powder form to be reconstituted with 4 liters of water (Pg. 657).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination sodium phosphate and PEG for use as a bowel cleanser. However, the prior art amply suggests the same as the prior art discloses the combination of PEG and sodium phosphate for use as a bowel cleanse. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would be effective as a bowel cleanser for use in clearing bowel prior to examination procedures and is well tolerated.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that there is no motivation to select PEG from the list set forth in WO 98/43654. However, as disclosed in Kaori et al., one of ordinary skill in the art would have been motivated to select PEG with the expectation that it would be well tolerated and resulted in satisfactory cleaning of the colon. Examiner acknowledges Applicant's arguments with respect to claim 25 of WO 98/43654, however, claim 25 is simply a description of an embodiment which is nonaqueous. However, as indicated above, use of aqueous formulations are disclosed in WO 98/43654 and Kaori et al.. There is no indication that it is the preferred embodiment. Even if it was the preferred embodiment, disclosed examples and preferred embodiments do not constitute

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a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

Examiner has duly considered Applicant's affidavit, however, in light of the addition of the new art which specifically discloses a method of cleaning the colon with the combination of sodium phosphate and polyethylene glycol electrolyte lavage which is well tolerated and satisfactorily cleans the colon, said affidavit is insufficient to overcome the claimed rejection. Further, with respect to Cleveland et al., Cleveland et al. is no longer part of the rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/43654 in view of Cleveland et al. (US Pat. 6,048,901), Wood et al. (US Pat. 5,498,425) and Vining (US Pat. 5,782,762) in further view of Sobrino-Faya et al. and Physician's Desk Reference (49th Ed. 1995).

WO 98/43654, Wood et al. (US Pat. 5,498,425) and Vining (US Pat. 5,782,762) are cited for the same reasons as above and are incorporated herein to avoid repetition.

Cleveland et al. teach that polyethylene glycol is effective in reducing intestinal gases, cramping and/or anorectal irritation associated with constipation and which can be exacerbated by use of laxatives (Column 1, lines 14-30). It is taught that the composition is preferably substantially free of ancillary electrolytes as salts may exert a constipative effect (Column 45-

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58). It is taught that the PEG polymer used is solid at room temperature and soluble with water and may be mixed with water or juice (Column 1, lines 58-68, Column 2, lines 1-20).

Sobrino-Faya et al. discloses the combination of 90 ml of a standard preparation of sodium phosphate with 1500 ml of PEG and that colonic cleansing tended to be better sodium phosphate and PEG versus sodium phosphate alone (Abstract).

Physician's Desk Reference (1995) discloses that 5 ml of regular or flavored Fleet® Phospho®-soda contains 2.4 g of monobasic sodium phosphate and .9 g of dibasic sodium phosphate and that 45 ml is used as a purgative (Pgs. 1018, 1019).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination sodium phosphate and PEG for use as a bowel cleanser. However, the prior art amply suggests the same as the prior art discloses the combination of PEG and sodium phosphate for use as a bowel cleanse. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would be effective as a bowel cleanser for use in clearing bowel prior to examination procedures, the combination with PEG would reduce any intestinal gas or cramping which may be exacerbated by use of laxatives, that lack of ancillary salts would increase laxative effect due to reduced constipation and that the combination of PEG and sodium phosphate would be effective cleansing the colon for colonoscopy.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that there is no motivation to select PEG from the list set forth in WO 98/43654. However, as disclosed in Sobrino-Faya et al., one of ordinary skill in the art would have been motivated to select PEG with the expectation that combination would be better than

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sodium phosphate alone. Examiner acknowledges Applicant's arguments with respect to claim 25 of WO 98/43654, however, claim 25 is simply a description of an embodiment which is nonaqueous. However, as indicated above, use of aqueous formulations are disclosed in WO 98/43654. There is no indication that it is the preferred embodiment. Even if it was the preferred embodiment, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

Further, with respect to Cleveland et al., Cleveland et al. does not teach away from the combination of PEG and sodium phosphate salts. Cleveland et al. discloses that the reason for preferably avoiding the use of ancillary electrolytes is because the salt may exert a constipative effect. However, the prior art discloses the use of sodium phosphate salts for cleansing the colon, as such, one of ordinary skill in the art would expect that sodium phosphate would not exert a constipative effect and, thus, could be combined with the PEG.

Examiner has duly considered Applicant's affidavit, however, in light of the addition of the new art which specifically discloses a method of cleaning the colon with the combination of sodium phosphate and polyethylene glycol which is better than the use of sodium phosphate alone, said affidavit is insufficient to overcome the claimed rejection. Although the benefits of combination of sodium phosphate and PEG versus sodium phosphate alone are not the same benefits as set forth in Applicant's affidavit, the benefits disclosed in Applicant's affidavit are insufficient to overcome the motivation to use the combination of sodium phosphate and PEG as

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disclosed in Sobrino-Faya et al. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. *In re Linter*, 173 USPQ 560 (CCPA 1972); *In re Dillon*, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30, 32, 33 of copending Application No. 10/194251. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 1-30, 32, 33 of the '251 application anticipate claims 1-36, 42, 43 of the present Application in that the '251 application claims amount ranges of the same components which fall within the ranges in the present application.

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Claims 37-41 are obvious of the claims of the '251 application in that the '251 application discloses amount ranges of the sodium phosphates and amount ranges of PEG which falls within the range of the PEG in the present claims. The difference between the claims of '251 application and the claims of the present invention is that the PEG is water-soluble and in a dry dosage form which is subsequently dissolved in water for use, whereas the claims of the present Application claim a PEG which liquid at room temperature and is in a liquid dosage form which optionally can be combined with an aqueous medium. However, it is well within the skill of one ordinary skill in the art to modify the prior art as above with the expectation that when the '251 application composition is dissolved in an aqueous medium for use, the PEG contained therein will be liquid at room temperature. As such, claims 37-41 are an obvious modification of the claims of the '251 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC

July 14, 2005



SABIHA QAZI, PH.D
PRIMARY EXAMINER